

Via ECF

April 21, 2023

Hon. Katherine Polk Failla
Thurgood Marshall
United States Courthouse
40 Foley Square
New York, NY 10007

*Re: In re: Chantix (Varenicline) Marketing, Sales Practices and Products
Liability Litigation (No. II), 22-MD-3050 (KPF), 22-mc-3050 (KPF) (S.D.N.Y.)*

Dear Judge Failla:

We are Temporary Plaintiffs' Counsel in the above-captioned action (the "Action"). Further to Your Honor's guidance at the April 7, 2023 initial pretrial conference, and Your Honor's order of the same day (*see* D.E. 30), we submit herein Plaintiffs' revised proposed leadership appointment request. This proposed structure is the same revised structure submitted in Plaintiffs' position in the parties' joint March 31, 2023 letter to the Court, and discussed at the ensuing April 7 conference.

Counsel for all Plaintiffs have re-conferred, and are pleased to report we have reached a consensus regarding the revised proposed leadership structure that we believe will achieve efficiency and economy in the prosecution of the Action, without jeopardizing fairness to the parties. Temporary Plaintiffs' Counsel now proposes three interim co-lead counsel (Ruben Honik of Honik LLC, Jorge Mestre of Rivero Mestre LLP, Charles Schaffer of Levin, Sedran & Berman) and one local New York attorney as liaison counsel (Joseph P. Guglielmo, of Scott+Scott L.L.P.). This structure is necessary and warranted for this Action given the complex claims asserted and broad scope of consumer and TPP clients representing the proposed Classes. The proposed structure will also provide the most resources to go head-to-head with one of the world's largest pharmaceutical corporations.

As set forth more fully below, Temporary Plaintiffs' Counsel respectfully requests that the Court enter the Proposed Order filed concurrently herewith.

I. Factual Background

For completeness, we recount the same case background presented in our March 17 letter.

Plaintiffs in the various actions are persons and TPPs that have purchased varenicline-containing medications under the brand name Chantix® ("Chantix") manufactured and sold by Defendant Pfizer, Inc. ("Pfizer"). Plaintiffs allege that during the Class Period, Chantix was contaminated with dangerously high levels of N-nitroso-varenicline, a carcinogenic substance.

Pfizer's drugs also were not manufactured in compliance with current Good Manufacturing Practices (cGMPs). Because nitrosamines are not active or inactive components of Chantix, the presence of nitrosamine contaminants in a drug such as Chantix, as well as Pfizer's significant cGMP violations, each rendered its product adulterated and misbranded under federal and analogous state laws, and therefore economically worthless and illegal to sell.

Certain Plaintiffs bring claims on behalf of TPPs that purchased Chantix, while other Plaintiffs bring claims on behalf of consumers of Chantix. Plaintiffs bring various claims on behalf of each of the Classes, including claims for breach of express and implied warranty, fraud, negligent misrepresentation and omission, violation of state consumer protection laws, violation of the Magnuson-Moss Warranty Act, negligence, negligence per se, and unjust enrichment.

On December 22, 2022, the Judicial Panel on Multidistrict Litigation issued a Transfer Order under 28 U.S.C. §1407 centralizing the various Chantix cases to the Southern District of New York, finding it would best promote the just and efficient conduct of this litigation. ECF No. 1.

II. The Proposed Structure Is Appropriate Structure Given the Complexity of the Claims

Temporary Plaintiffs' Counsel believes that the proposed structure is the best way to successfully litigate the Action and receive the best recovery for Plaintiffs and the Classes. Given the complexity of the claims, the number of claims alleged, and the sophistication of the clients involved, the three-tiered structure will maximize recovery, while ensuring efficient prosecution of the claims. Because both consumers and TPPs are bringing claims against Pfizer, having a leadership structure as proposed will best ensure that both Classes are fairly represented at each stage of the proceedings. Mr. Honik represents the majority of consumers plaintiffs in this Action. Messrs. Mestre and Schaffer represent, respectively, the first and second TPP plaintiffs to have filed cases. Mr. Guglielmo also represents a TPP plaintiff, and as local New York attorney who has long-practiced in this District he is well-situated to serve as liaison counsel. To date, all four individuals have capably worked together and with other Plaintiffs' counsel to work with all Plaintiffs' Counsel, work to achieve consensus, to steer this Action efficiently for the plaintiff's side.¹

¹ Courts routinely have appointed similar structures in complex MDLs involving drug products. *See, e.g.*, Case Management Order No. 6 Approving Plaintiffs' and Defendants' Leadership Structure, *In re: Valsartan Products Liability Litig.*, No. 1:19-md-02875-RBK-JS, ECF No. 96 (D.N.J. May 6, 2019); Order Appointing Counsel, *In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, ECF No. 40 (D. Kan. Sept. 12, 2017) Supplemental Pretrial Order #8, *In re Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Prods. Liability Litig.*, No. 2:21-mc-1230-JFC, ECF No. 395 (W.D. Pa. Feb. 15, 2022); *Diaz v. Univ. of S. Cal.*, No. 20-cv-4066, 2020 WL 5044419, at *4 (C.D. Cal. July 17, 2020).

Because Pfizer is a large corporation with substantial resources and top-tier representation, the proposed structure also ensures that Plaintiffs will have the necessary resources to litigate the Action. By appointing a three-firm Interim Co-Lead Counsel structure, with one Liaison Counsel, Plaintiffs will have the essential lawyers and capital needed to oppose Pfizer.

Each firm selected to serve in the proposed structure will play a specific, yet vital role in the prosecution of the Action. During all phases of the litigation, Interim Co-Lead Counsel will: (i) organize and supervise the efforts of plaintiffs' counsel in a manner to ensure that plaintiffs' pretrial preparation is conducted effectively, efficiently, expeditiously, and economically; (ii) delegate work responsibilities and monitor the activities of plaintiffs' counsel to assure that schedules are met and unnecessary expenditures of time and expense are avoided; (iii) speak for plaintiffs at all court conferences and hearings; (iv) initiate and conduct discussions and negotiations with counsel for Pfizer on all matters, including settlement; (v) determine (after consultation with other co-counsel as may be appropriate) and present in briefs or oral argument to the Court and opposing parties the position of the Plaintiffs on all matters arising during the proceedings; (vi) enter into stipulations with opposing counsel as necessary for the conduct of the litigation; (vii) select, consult with, and employ experts, as necessary, for Plaintiffs; (viii) initiate and conduct discovery on Plaintiffs' behalf, and coordinate its efficiency; (ix) serve as the primary contact for all communications between Plaintiffs and Pfizer; (x) coordinate the work of preparing and presenting all of Plaintiffs' claims and otherwise coordinate all proceedings; (xi) encourage and enforce efficiency among all Plaintiffs' counsel; (xii) assess Plaintiffs' counsel for the costs of the Action; and (xiii) perform such other duties in connection with prosecuting the claims in this Action.

Liaison Counsel will be responsible for performing the duties and responsibilities described in the MCL 4th §10.221, including facilitating and expediting communications with and among Plaintiffs' counsel and fulfilling such other duties as requested by the court or Interim Co-Lead Counsel. Liaison Counsel will also assume responsibility for the following: (i) receiving orders, notices, correspondence, and telephone calls from the court and the clerk of the court on Plaintiffs' behalf; (ii) preparing and transmitting copies of such orders and notices on Plaintiffs' behalf; (iii) receiving orders and notices from the Judicial Panel on Multidistrict Litigation; (iv) maintaining complete files with copies of all documents served and make such files available to Pfizer's counsel on request; (v) maintaining and making available to all counsel and the Court an up-to-date service list; and (vi) accepting service for all plaintiffs in all cases of notices, orders, pleadings, motions, discovery, and memoranda. Liaison Counsel will also handle administrative matters, as well as any substantive matters which Interim Co-Lead Counsel may assign.

To ensure that the work performed by Interim Co-Lead Counsel and Liaison Counsel, is performed effectively and efficiently without unnecessary duplication, we propose a time and expense protocol be implemented for work performed by counsel for Plaintiffs in the Action. Reports of time and expenses can be submitted *in camera* to the Court for review on a semi-annual or quarterly basis. This will allow Interim Co-Lead Counsel to ensure each month that the firms are only completing authorized and approved work, as well as reject any unauthorized time.

Periodic *in camera* time and expense submissions, while more work for Plaintiffs' counsel, also ensures accountability and reduces the likelihood of disputes about costs or fees at the conclusion of this matter. In addition, the Court can confirm that the time and expenses incurred are reasonable and for the benefit of the Classes.

III. Because The Various Plaintiffs Firms Agree to the Proposed Structure, The Court May Enter the Proposed Order

Here, the various Plaintiffs have consented to this "private ordering." *Manual for Complex Litig.* §21.272 (private ordering is when "lawyers agree who should be lead class counsel and the court approves the selection after a review to ensure that the counsel selected is adequate to represent the class interests"). Such private ordering is the most common and desirable means of selecting class counsel. *See id.* at §10.22 (efforts by attorneys to "coordinate their activities without the court's assistance . . . should be encouraged"); *In re Cmty. Bank of N. Va. Mortg. Lending Practices Litig.*, MDL No. 1674, 2011 WL 4382942, at *2 (W.D. Pa. Sept. 20, 2011) ("[T]he private ordering method of selecting interim lead counsel has long been the preferred approach."). Thus, the Court may enter the Proposed Order without further submissions from counsel.

For the foregoing reasons, Temporary Plaintiffs' Counsel request that the Court appoint a single group of counsel to represent the proposed Classes, comprised of a three-firm Interim Co-Lead Counsel and a single firm Liaison Counsel.

Temporary Plaintiffs' Counsel already submitted the biographies, certificates of good standing, and other requested materials for Messrs. Honik, Mestre, Schaffer, and Guglielmo with the under-seal March 17 submission, but are happy to re-submit those materials as directed by the Court.

Respectfully,



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cc: All Counsel of Record (via ECF)